REMARKS

Claims 1 – 12 and 15 – 20 are currently pending. Of these, Claims 1, 15, and 16 are independent claims. In response to the Office Action, new dependent claims 18 - 20 have been added, and claims 1, 15, and 16 have been amended. No new matter has been introduced into the case by the amendments or by new claims, all of which are supported by the original disclosure. All rejections are respectfully traversed, and favorable reconsideration is requested in view of the above amendments and following remarks.

In the most recent Office Action, the Examiner rejected all pending claims on the alleged ground that the subject matter of these claims would have been obvious to a person of ordinary skill in the art from what is described in U.S. Patent No. 5,498,788 to Zmitek et al. ("Zmitek") plus what is described in the Buckton et al. reference ("Buckton"), U.S. Patent No. 5,585,115 to Sherwood et al. ("Sherwood"), and the Czap reference ("Czap"). Implicit in this is an assertion that this art would have predisposed or somehow motivated this hypothetical person of ordinary skill in the art to combine selected parts of these references to produce what Applicants are claiming. However, contrary to the Examiner's contentions, the art does not suggest the subject matter of the claims. As will be shown below, the rejections are not well taken, and should be withdrawn.

Applicants first note that both box 2a and box 2b were checked on the Office Action Summary sheet, indicating that the Office Action was, at once, both Final and Non-final. Of course, this is not possible. The Action must be one or the other, but not both. However, since new art was cited and the USPTO PAIR system states that a "Non-Final" action was mailed on May 7, 2008, it seems reasonable to assume the action was in fact Non-Final.[1]

Claims 1, 15, and 16 each call for, *inter alia*, a pharmaceutical tablet which comprises amoxicillin, clavulanic acid and silicified microcrystalline cellulose or "SMCC." It is a feature of the invention that the tablets as claimed are "substantially free of superdisintegrants." This is not disclosed or suggested by the cited art.

[1] Additionally, Laura Luethke, Assistant to Mark Graham, called Examiner Choi on May 13, 2008, and he confirmed this action was a non-final rejection.

The Examiner continues to point to Example 10 of Zmitek (Col. 11, lines 5 – 31), which he contends discloses a dispersion tablet containing amoxicillin, potassium clavulanate, and microcrystalline cellulose (MCC). He concedes the Zmitek formulation contains no SMCC. But he contends it would have been obvious to a person of ordinary skill to substitute SMCC in place of MCC because of what is said in Buckton.[2] He also contends the Zmitek formulation is substantially free of any superdisintegrants. As will be shown, this is incorrect.

While Applicants disagree that Buckton would lead a person of ordinary skill to substitute SMCC for SMC in the Zmitek formation, the fact is it does not matter. A person of ordinary skill in the pharmaceutical arts would know at least two things about crospovidone that would prevent them from considering the formulation of Zmitek containing 1-2 wt. % crospovidone as a composition that contains "substantially no superdisintegrants" according to Applicants' claims.

First, a person of ordinary skill would know that crospovidone is a super-disintegrant. This is undisputed.

Second, the person of skill would know the amount of crospovidone used in Zmitek is a substantial amount of a superdisintegrant consistent with amounts used to provide the superdisintegrant function. For example, U.S. Patent No. 6,660,330 entitled "Pharmaceutical Superdisintegrant" to Staniforth describes that superdisintegrants are referred to as 'super' "because of their high efficiency, *even at low concentration . . . .*" '330 patent, Column 3, lines 44-45 (emphasis added). The '330 patent specifically refers to a superdisintegrant known as Croscarmellose Sodium (a.k.a., "Ac-Di-Sol"); *"[t]he amount of Ac-Di-Sol used in direct compression tableting may vary with typical usage levels* ***between 1 and 3 percent****."* '330 patent, Column 4, lines 4-6.

Thus, it is known to those of ordinary skill that superdisintegrants such as crospovidone are conventionally used in relatively small amounts to provide "super-

[2] It is Applicants' understanding that Czap is cited only for its alleged disclosure of hydrogenated castor oil as a lubricant in an effort to meet what is called for in dependent Claim 12. Thus, Applicants' have focused solely upon Zmitek, Buckton, and Sherwood with respect to the patentability of the independent claims.

disintegration." So, the 1 to 2 wt % crospovidone described in Zmitek is consistent with what would be understood as an effective amount to confer superdisintegrant properties and functionalities.

Accordingly, a person of ordinary skill in the art would know the amounts of 1 to 2 wt. % of crospovidone present in compositions like those of Zmitek are indeed functional amounts of a superdisintegrant and NOT "impurity" or "trace" amounts, and that such references do not teach or suggest compositions which have substantially no superdisintegrants as called for in Applicants' claims.

The deficiencies of Zmitek should now be apparent beyond peradventure. Buckton, Sherwood, and/or Czap add nothing relative to Zmitek. Thus, claims 1, 15, and 16 patentably distinguish from Zmitek, Buckton, Sherwood, and/or Czap. Reconsideration and allowance of claims 1, 15, and 16 are respectfully requested.

Dependent claims 2 – 12 and 17 - 20 depend from allowable independent claims as discussed above, but they specify additional important aspects of the various embodiments of Applicants' disclosure not described or suggested in the cited art. Therefore, dependent claims 2 – 12 and 17 - 20 should be allowed as well.

In light of the foregoing, Applicants once again urge the Examiner to reconsider the application, to withdraw all rejections, and to issue a notice of allowance at the earliest possible convenience.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

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